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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,459	06/14/2001	Hiromi Ikadai	0020-4843P	7623

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EXAMINER
BASKAR, PADMAVATHI

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 01/22/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/807,459	IKADAI ET AL.	
	Examiner	Art Unit	
	Padmavathi v Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *1-3, 7-10 and 12-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-6 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-13* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's response to restriction filed on 10/16/02 (paper No 14) is acknowledged. Claims 1-13 are pending in the application.

Priority

2. This application is a national stage entry of PCT/JP99/04386 (08/13/1999).

Drawings

3. The drawings are accepted by the draftsperson under 37 C.F.R. 1.84 or 1.152. Applicant should comply with the objections to the drawings as set forth in Form- 948 (Draftsperson's Notice) mailed with this Office action.

Information Disclosure Statement

4. Information Disclosure Statements filed on 4/13/01 (Paper # 8) and 6/26/01 (Paper # 10) are acknowledged and a signed copy of each is attached to this Office action.

Election

5. Applicant's election of Group II claims 4-6 and 11 (recombinant protein) in Paper No 14 (10/16/02) without traverse is acknowledged. Claims 1-3, 7-10 and 12-13 are withdrawn from consideration as non-elected invention.

Specification Informalities

6. Claims shoud begin with "I claim" or "'we claim" or "What is claimed is".

Claim Rejections - 35 USC 112, first paragraph

7. Claims 4-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated recombinant protein, said protein has the amino acid sequence shown in SEQ.ID.NO: 2 does not reasonably provide

enablement for recombinant protein, where in said recombinant protein has the amino acid sequence shown in SEQ.ID.NO: 2 with one to several amino acid residues therein being deleted, substituted or added. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification is not enabled for a recombinant protein which has the amino acid sequence shown in SEQ.ID.NO: 2 with one to several amino acid residues therein being deleted, substituted or added because It is unclear to one skilled in the art what amino acids have been deleted or added or substituted in SEQ.ID.NO: 2. If it is unclear to one skilled in the art what amino acid sequences are embraced after these modifications which is based on a specification, the specification is non-enabling, since one skilled in the art would not be able to make and use those sequences without undue experimentation.

It is well known that for proteins, for example, even a single amino acid change can destroy the function of the biomolecule. The effects of these changes are largely unpredictable as to which ones have a significant effect versus not. Further, specification is silent on how to make these proteins with sequence homology or variants or fragments. What changes would have an adverse effect on the function of this peptide is not predictable. It is known in the art that derivatives or variants, which are obtained by substitutions, deletions, or modifications of the amino acids of a protein, alter the function of the protein. The amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and still retain similar activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expected intolerant to modification), and

detailed knowledge of the ways in which the proteins' structure relates to its function. However, the problem of predicting protein structure from mere sequence data of a single protein and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein and finally what changes can be tolerated with respect thereto is extremely complex (Bowie et al. Science, Vol. 247: 1990; p. 1306; p. 1308) and is well outside the realm of routine experimentation.

Claim Rejections - 35 USC 112, second paragraph

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

9. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is vague in reciting " from a host transformed with a DNA vector----." Does applicant intend " in a host cell transformed----."

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

11. Claims 4, 5 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Bose et al 1992 (International Journal of Parasitology, 22; 627-630).

Claims are directed to recombinant protein from merozoites of B.caballi, said recombinant protein has the amino acid sequence shown in SEQ.ID.NO: 2. Claim is also drawn to an antigen comprising the recombinant protein.

Bose et al ~~et al~~ disclose 48KD and 50KD proteins from B.caballi and are immunologically reactive with infected horse sera (see page 629, under Discussion, abstract and figure 1). In the absence of evidence to the contrary, these proteins contain the amino acid sequence as shown in SEQ.ID.NO: 2. Claims 4, 5 and 11 are drawn to recombinant proteins based on product-by-process limitations. Although product-by-process claims are limited and defined by the process, nonetheless, determination of patentability is based on the product itself. The patentability of a product does not depend upon its method of production. If the product in the product-by-process claim is the same as or an obvious variant of the product of the prior art, the claim is unpatentable even though a different process made the product. Multiple routes can obtain the recitation of a process limitation in claims "recombinant" is not seen as further limiting the claimed product, as it is presumed the equivalent products. Where a product-by-process claim is rejected over a prior art product that appears to be identical, although produced by a different process, the burden is upon the applicants to provide evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Thorpe*, 227 U.S.P.Q. 964, 966 (Fed. Cir. 1985). *In re Marosi*, 218 U.S.P.Q. 289, 293-293 (C.A.F.C. 1983). *In re Best*, 195 U.S.P.Q. 430, 433 (C.C.P.A. 1977). *In re Brown*, 173 U.S.P.Q. 685, 688 (C.C.P.A. 1972).

12. Claims 4 -6 and 11 are rejected under 35 U.S.C. 102(a) as being anticipated by Kappmeyer et al 1999 (Journal of Clinical Microbiology, 37; 2285-2290).

Claims are directed to recombinant protein from merozoites of B.caballi, said recombinant protein has the amino acid sequence shown in SEQ.ID.NO: 2, said recombinant protein is expressed in host cell tranfected with DNA vector encoding the amino acid sequence as shown in SEQ.ID.NO: 2. Claim is also drawn to an antigen comprising the recombinant protein.

Kappmeyer et al disclose a cDNA encoding protein RAP-1 obtained from merozoites of B.caballi (abstract), said recombinant cDNA encodes the protein which has an amino acid sequence SEQ.ID.NO: 2 (see page 2287, left column) as shown in AF092736 (full-length clone) and AF092735 (truncated clone).

This recombinant RAP-1 protein is immunologically reactive with a monoclonal antibody79/17.18.5 (see abstract and figure 1) and thus read as an antigen. Further the prior art disclose RNA isolation and gene cloning. Total RNA was isolated from infectedRBCs. Poly (A) RNA was purified from the total RNA by and a oligo (dT) selection method (Pharmacia), cDNA synthesis was also performed and the resulting cDNAs were ligated into the bacteriophage lambda ZAP II vector (Stratagene). The amplified library was screened for expression of proteins reactive with MAb 79/17.18.5). Recombinant pBluescript plasmid containing clones were recovered from plaque-purified lambda phage by in vivo excision. Bacterial lysate containing recombinant protein was produced following transformation of competent E. coli DH5 with 1 ng of the recombinant pBluescript plasmid (see under page 2286, left column, under gene cloning and recombinant antigens) and thus read on the recombinant protein that is expressed in host cell transfected with DNA vector. Thus the prior art anticipated recombinant protein or antigen comprising the recombinant protein from merozoites of B.caballi.

13. Claims 4 -6 and 11 are rejected under 35 U.S.C. 102(a) Ikadi et al1998 as being anticipated by (Accession No: ABO17700 or Abstract of 126 th conference on Japanese Society of Veterinary Science)

Ikadi et al disclose a cDNA expression library prepared from Babesia caballi merozoite mRNA and was screened with a monoclonal antibody against the rhoptry protein of B. caballi merozoite. A cDNA encoding a protein was designated BC48. This

sequence contained an open reading frame with a nucleotide sequence that encodes the disclosed recombinant protein (see Accession No: ABO17700) and thus read on antigen comprising the recombinant protein from merozoites of B.caballi.

Status of Claims

14. No claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D

12/2/02.

LYNETTE R. F. SMITH
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